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## TELECARE

### PORTABLE MEDICAL STATUS SYSTEM

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### SAFETY ASSESSMENT REPORT



*National Aeronautics and Space Administration*  
**LYNDON B. JOHNSON SPACE CENTER**  
*Houston, Texas*

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JSC 10753

TELECARE

PORTABLE MEDICAL STATUS SYSTEM

CONTRACT NAS 9-14334

SAFETY ASSESSMENT REPORT

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This report identifies the hazards inherent to the Portable Medical Status System, and where appropriate, describes the measures taken to reduce them to an acceptable level. The report is a prerequisite to use of the system on humans in the earth environment.

The investigation identified one hazard which is insufficiently controlled and which is considered a constraint to use on humans. The level of current possible in the electrodes for the EEG (electroencephalograph) circuitry exceeds the maximum specified by JSCM 8080, JSC Design and Procedural Standard 131.

A number of procedural and design recommendations for enhancement of safety are made. Non-compliance with these except for that referenced to JSC Standard 131, is not considered a constraint to use of the prototype unit for JSC tests using human subjects.

The system is considered to be safe for testing on JSC subjects following satisfaction of the requirements of JSC Standard 131.

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## 2.0

### INTRODUCTION

2.1 PURPOSE. This report provides an assessment of the results of a hazard analysis performed in preparation for operational use of the Portable Medical Status System prototype. The system constitutes a hand-carried device for on-the-scene determination of victim status.

2.2 SCOPE. This report assumes usage of the system in an earth environment, and includes an assessment of all major features, functions, supplies, accessories, and supporting equipment contained in the Portable Medical Status System. The assessment of supplies and accessories (see paragraph 3.4) addresses their capability for impairing system operability and hazards to the victim/subject if the supplies and accessories become lost, due to insufficient control. The unit was manufactured by Telecare, Inc., Houston, Texas. The analysis consists of a review of available descriptive literature, schematics, layouts, and hardware. Assistance was provided by Telecare, Inc., personnel in describing and demonstrating the equipment and explaining the drawings. No operating procedures were provided.

This analysis seeks to identify all sources of hazard related to the usage of the system; i.e., it attempts to identify, in addition to the ways the system can harm the victim, ways in which the victim can be harmed by outside sources working through the system. Consideration is given to failures and effects which would create hazards to the victim through failure of the unit to function correctly. Although primary attention is given to hazards in the use of the prototype system during JSC testing, potential hazards in the usage of production units are also identified.

3.0 HAZARD ANALYSIS. Results of the hazard analysis of the Portable Medical Status System are described in subsequent paragraphs. A brief description of each element of the equipment and the method of operation is followed by an assessment of safety-related characteristics of each item of equipment.

The equipment provides capability for measurement of body temperatures, heart rate, respiration rate, and recording of electrocardiograph (ECG) and electroencephalograph (EEG) data. Interface of the victim with the electrical components is limited to the thermometer probe, the ECG/EEG electrodes, and the blood pressure cuff/microphone.

Outputs are provided to a small tape recorder, an ECG recorder, and to a telephone line (optional).

Power is provided by a battery installed in the carrying case.

### 3.1 MEDICAL SUPPORT EQUIPMENT

3.1.1 Thermometer. The thermometer probe is a commercially available unit, unmodified for this application.

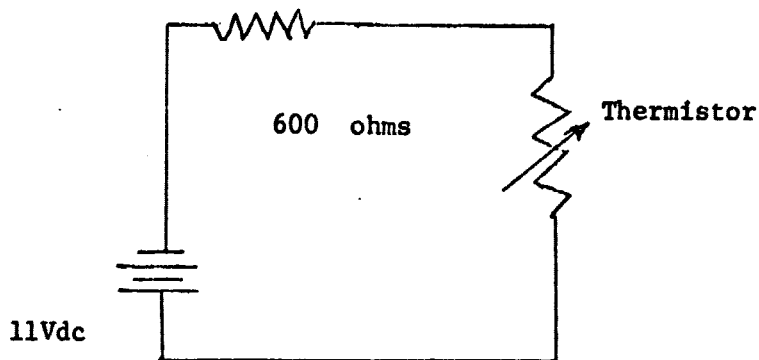
Metallic components are insulated by a plastic coating. Electrically, the temperature sensor is a heat-sensitive resistor (thermistor) in series with a fixed 600 ohm resistor, connected across a source of 11 volts d.c. Analysis of the circuitry shows that at least three failures of insulation and components are required before the battery voltage (14 Vdc) is applied to the patient.

Measurements made at Telecare, using the prototype thermometer and a digital ohmmeter gave the following readings. The ohmmeter leads were connected to the plug on the probe cable.

Ambient room temperature: 16K ohms

In mouth of subject: 7K ohms

Assuming the following circuit configuration:



Current through probe at ambient: .0006 amperes  
Current through probe in mouth: .0015 amperes  
or 600 and 1500 microamperes, respectively.

Any residual shock hazard from the thermometer probe is considered acceptable because of the low probability of occurrence, the low level of worst case voltage, low duty cycle of applied voltage (.005%), and the placement of the probe. Application of resultant currents to the mouth, face, or finger areas is not considered hazardous.

3.1.2 Blood Pressure. Blood pressure circuitry utilizes inputs from a standard Skylab-type cuff/microphone. The cuff is inflated and deflated manually by the operator. The microphone, in addition to its normal internal insulation is further isolated from the victim by materials in the cuff pocket. No voltages are applied to the cuff or to the microphone. No credible shock hazard was identified for this system element or its supporting electronics.

3.1.3 Respiration Rate. The respiration rate portion of the circuit utilizes impedance pneumography. Data is processed from the same electrodes used for the transduction of the ECG and EEG. Data is derived from changes in impedance of the victim's chest to a 50 kHz constant current signal fed through the electrodes. The occurrence of respiration is detected, the interval between breaths measured and a rate computed and displayed. Current levels for the 50 kHz signal are limited to 500 microamperes (.0005 Amperes).

No shock hazard was found in the pneumograph circuitry.



Rationale and data for the usage of the 50 kHz signal at the electrodes is found in "Response to Passage of Electric Current Through the Body," by L. A. Geddes and L. E. Baker, Baylor College of Medicine, Houston, Texas, (see Appendix A). The authors concluded that current levels sufficient to cause ventricular fibrillation in humans and animals increase significantly with frequency. For example, it was determined that, for a 150 pound subject, with transthoracic electrodes applied, a 10 kHz, 11 ampere signal would be required to produce ventricular fibrillation. It was also determined by extrapolation that higher frequencies, such as 50 kHz, would require still higher current levels.

Purity of the sinusoidal waves used was not specified in the study. If the conclusions from the study are accurate, it can be stated that for a wave with a fundamental frequency of 50 kHz, any harmonic frequencies present would tend to be reduced in their effect by the increased impedance of the body structure at those higher frequencies, and would not degrade safety. Safety would be degraded seriously, however, if a significant level of 60 Hz energy from the 117 Vac input appeared on the electrodes in parallel with the 50 kHz signal as the result of component failure, capacitive coupling, design error, or for any other reason.

Geddes and Baker concluded that for the 150-pound subject referred to above, the immunity to 50 kHz current was considerably higher (by a factor of 58.6) than the tolerance to 60 Hz current.

For the purpose of this hazard analysis it is concluded that the 500 microampere, 50 kHz signal used in the impedance pneumograph is not hazardous to JSC test subjects. It is also concluded that the hazard for 60 Hz power line current is reduced to an acceptable level by the design, by conformance with the recommended procedural additions and by implementation of the recommended control panel decal.

3.1.4 Electrocardiograph/Electroencephalograph. Electrical signals generated by heart and brain activity are detected and displayed.

No shock hazard to the patient was identified in the internal circuitry.

The level of current present at the electrodes for the ECG is above the maximum specified in JSC Standard 131, and is therefore unacceptable, and considered a constraint to operational use. Calculated maximum current for the ECG electrodes is 300 microamperes dc, as compared with the 100 microampere maximum level allowed by the standard.

3.1.5 Audio Coupler. Use of the audio coupler provides the transfer of audio frequency information from the system to a commercial telephone line without making electrical connections. The coupler is simply attached to the mouthpiece of an ordinary telephone handset. The transducer is mounted in a cuff of heavy insulation and is considered to present no hazard.

3.2 RECORDING EQUIPMENT. Two recorders are used:

a. A cassette tape recorder is provided for voice or other recording.

b. An ECG recorder utilizes standard ECG chart paper.

Neither recorder is considered to present any personnel hazard.

3.3 POWER SUPPLIES. Power during operational use is supplied by a sealed lead-acid battery, using jell electrolyte to minimize spillage or leakage. Provision is made for hydrogen venting during the charging cycle, and circuitry is provided to control charging current so that inadvertent prolongation of charging time will not damage the battery. The charger is powered from 117 Vac and is an integral part of the system.

Hazards from 117 Vac have been reduced by providing capability in the charger switching for positive disconnection of the battery output to the medical electronics, isolation of battery charger circuitry, and grounding of the aluminum case to the 117 Vac neutral wire. Replacement of the aluminum carrying case with a non-conductive material is recommended as a safety enhancement measure. In spite of existing design and procedures safeguards, there is a remaining set of hazards related to the potential presence of 117 Vac at the power switch terminals. Admittedly the probability of occurrence of the failures and circumstances necessary to create electrical shock to the patient, with or without the electrodes attached, is low. All of these concerns, however, can be eliminated by providing an interlock such that 117 Vac cannot be present under any reasonable circumstances. For example, the 117 Vac power cable could terminate, at the system end, in a multiple female plug which must be removed before the plug for the electrodes could be inserted. It is recommended that in production models a suitable interlock be provided for this purpose. Procedural measures will reduce this hazard to an acceptable level during JSC testing.

3.4 ACCESSORIES AND SUPPLIES. In addition to the electronics equipment described above, an assessment was made of the medical supplies and accessories expected to be stored or deployed in the carrying case.

Included are various medical instruments, dressings, drugs, and chemical compounds used in emergency treatment.

These medications will vary with the personal preferences of the physician.

The hazards identified for the medical accessories are easily controlled. Degradation of electronic circuitry due to leakage of liquids can be controlled by careful attention to packaging prior to deployment and removal during non-operational periods.

Loss of capability to render maximum medical aid due to loss of drugs due to pilferage will be eliminated by following the procedures for the storage and control of prescription drugs.

3.5 PACKAGING. The system is housed in a aluminum carrying case similar in size to a conventional over-night bag. The container is compartmented for electronics, batteries, stowage of necessary flexible cables and probes and storage of drugs and related items for administering the drugs. No hazard to victim or operating personnel was noted.

3.6 OTHER SAFETY CONSIDERATIONS. Failure of the system to function adequately can degrade or negate the ability of the operator to diagnose, resulting in possible hazard to the victim.

Causes of such failure include:

1. Battery failure, due to improper charging procedures, failure to perform charging, to improper battery maintenance during extended periods of non-use, or to inability to assess battery condition.

2. Circuit Failure

3. Change in electrical characteristics of components.

4. Effects of spillage of liquids stored or deployed in the carrying case.

Since loss of diagnostic capability by the medical operator due to failure of the system to function creates additional hazard to the victim/subject, it is recommended that provision be made in the design of the system for assessment by the operator, prior to each usage, of the capability of the system to function as intended.

**3.7 PROCEDURES.** No operational or maintenance procedures have been provided.

It is recommended that the operational procedures include:

1. Caution notes against connection to 117 Vac with system connected to victim.
2. Caution notes against prolonged storage with batteries in place.
3. Directions for control of prescription drugs.

Maintenance procedures should provide:

1. Instructions for verifying operability prior to deployment or usage.

Instructions for proper disposition of liquid accessory items during storage periods.

**4.0 CONCLUSIONS AND RECOMMENDATIONS.** The Portable Medical Status System, properly configured, maintained and operated, should present no hazard to operator or test subject.

The following recommendations are made:

1. Modify the ECG circuitry to comply with electrical shock current levels of JSC Standard 131.

2. Provide in the design and procedure the means for assessment by the operator, prior to each usage, of the operational status of the system.

3. Provide, in the design or procedures, protection against the hazard to the system due to leakage of electrolyte from the lead-acid battery or from leakage or spillage of corrosive or electrically conductive materials stored and transported as medical supplies.

4. Stipulate in the JSC test procedures that connection to 117 Vac never be performed with electrodes attached to the subject, and provide a control panel decal cautioning against such action.

5. Provide a non-conductive carrying case for the system.

6. Provide procedures for battery charging and maintenance during periods of non-use.

7. Consider isolation (from susceptible system elements) of all corrosive materials deployed or stored within the carrying case.

8. For production models, provide an interlock so that 117 Vac cannot be connected to the system when electrodes are connected to the system.

Recommendation 1, above, is considered a constraint to use upon a human. Non-compliance with the other recommendations is not considered a constraint to testing with a JSC subject.

**APPENDIX A**

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# RESPONSE TO PASSAGE OF ELECTRIC CURRENT THROUGH THE BODY\*

L. A. Geddes, M. E., Ph. D.<sup>1</sup> and L. E. Baker, Ph. D.<sup>2</sup>

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Running head: Response to alternating current.

## ABSTRACT

In many of the techniques in which electric current is passed through the body to measure physiological events, the safe and dangerous levels have not been determined. This paper presents data on the threshold current for sensation and ventricular fibrillation.

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# RESPONSE TO PASSAGE OF ELECTRIC CURRENT THROUGH THE BODY\*

L. A. Geddes, M. E., Ph. D.<sup>1</sup> and L. E. Baker, Ph. D.<sup>2</sup>

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## INTRODUCTION

A remarkable number of physiological events can be detected easily by the impedance change appearing between electrodes placed on the surface of the body of man and animals. Among these are respiration, the volume of blood ejected with each heart beat, pulsatile blood volume changes in the head and body segments, eye movements, and the electrodermal response (GSR); reports on the various techniques have been presented by Atzler (1932, '35), Nyboer (1944, '59), Whitehorn (1949), Polzer (1961), Jenkner (1959, '62), Yokota (1962), Geddes et al. (1962, '63, '64, '68, '69), Sullivan (1963), Lifshitz (1963), Allison (1964, '66), Kubicek (1964, '66, '67), Martin (1965), Markovich (1965), Baker et al. (1965, '66, '70), and Lechner (1969).

Measurement of an impedance change requires the intentional passage of current through living tissue and, accordingly, care must be exercised in choice of the frequency and intensity of the current employed. Sensory receptors, nerve endings and fibers, glands, skeletal and smooth muscle are irritable tissues through which the current may flow. Stimulation of these tissues should be avoided, but beyond this consideration is the safety of the subject since in many instances some portion of the current also passes through the heart with the attendant danger of ventricular fibrillation. It is the purpose of this paper to assign magnitudes to several of the responses produced by the passage

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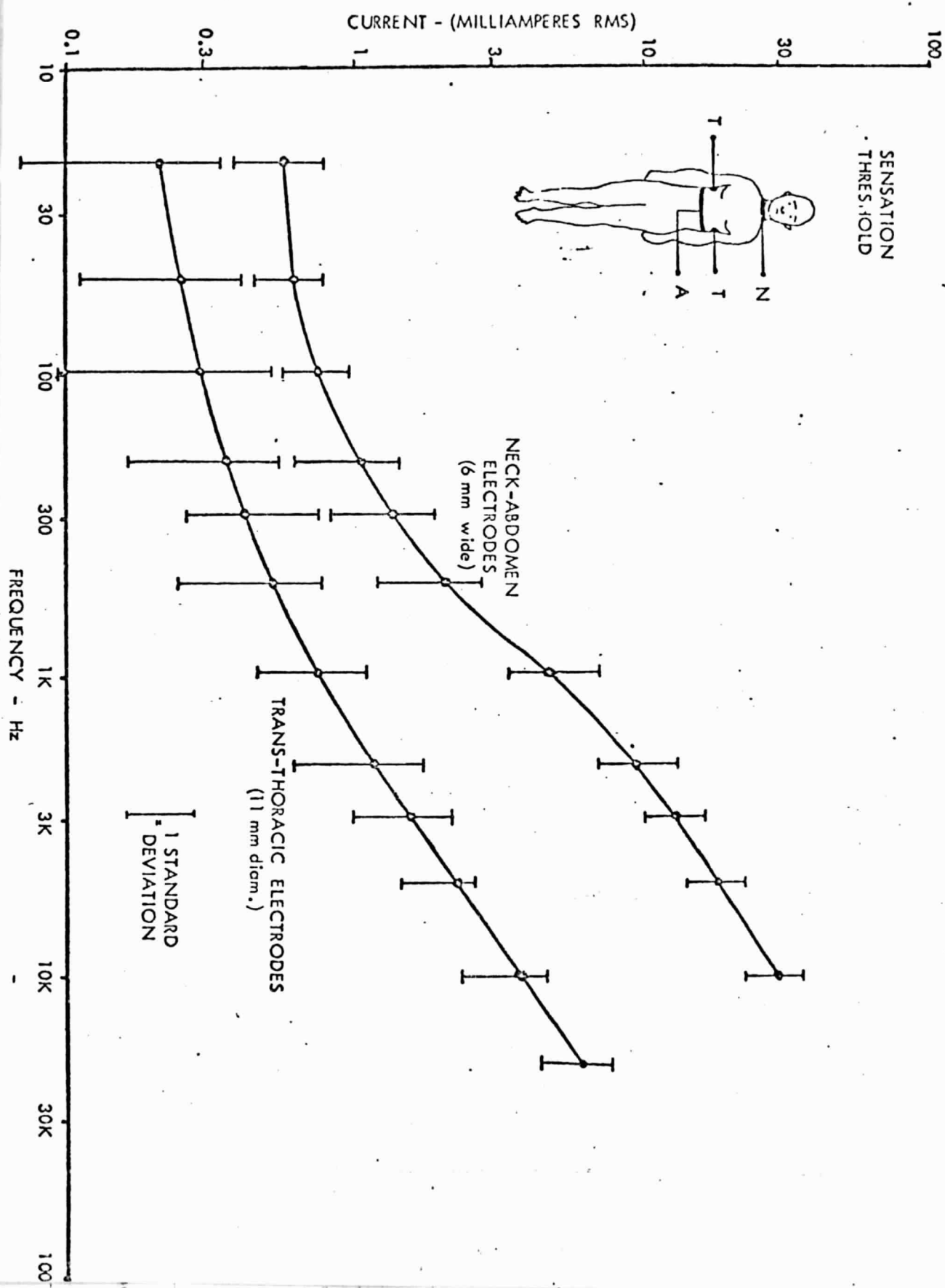
2 Associate Professor of Physiology, Baylor College of Medicine.

of sinusoidal alternating current through human subjects and animals.

### SENSATION THRESHOLD

The parameters of an effective stimulus are intensity and duration. Values for these are described by strength-duration curves which are specific for different tissues and identify the intensity and duration of current required for stimulation. Typical strength-duration curves for the irritable tissues previously mentioned rise steeply as duration is decreased, i. e., the shorter the duration, the higher the intensity required for stimulation. For example, for smooth muscle, stimuli shorter than 100 ms must have high current values to produce an effective stimulus. For nerve, skeletal muscle and cutaneous receptors, stimuli below 0.2 ms require an increasing intensity as duration is decreased. In fact, stimulation of highly irritable tissues such as nerve, cannot be achieved even with very short-duration pulses; therefore, when sinusoidal alternating current is used to measure impedance changes, the frequency chosen should be high, so that the duration of a single current pulse is short. Since the cutaneous receptors appear to have a very low threshold to electrical stimulation, it is expected that they would provide a guide to the choice of a suitable frequency for the current required to measure physiological events by impedance change.

The intensity of current necessary for perception was measured on eight normal human male subjects with electrodes placed in the locations used to measure respiration (Geddes, et al., 1962 and Baker et al., 1965, '65), and stroke volume (Kubicek et al., 1964, '66, '67). Fig. 1 (insert) illustrates the electrode locations. The transthoracic electrodes were 11 mm circular chlorided silver disks which made contact with the



thorax through a 1 mm thick film of electrode jelly. The electrodes encircling the neck and abdomen were aluminum ribbon 6 mm wide. A thin film of electrode jelly was applied to the ribbon to ensure good and uniform electrical contact with the skin.

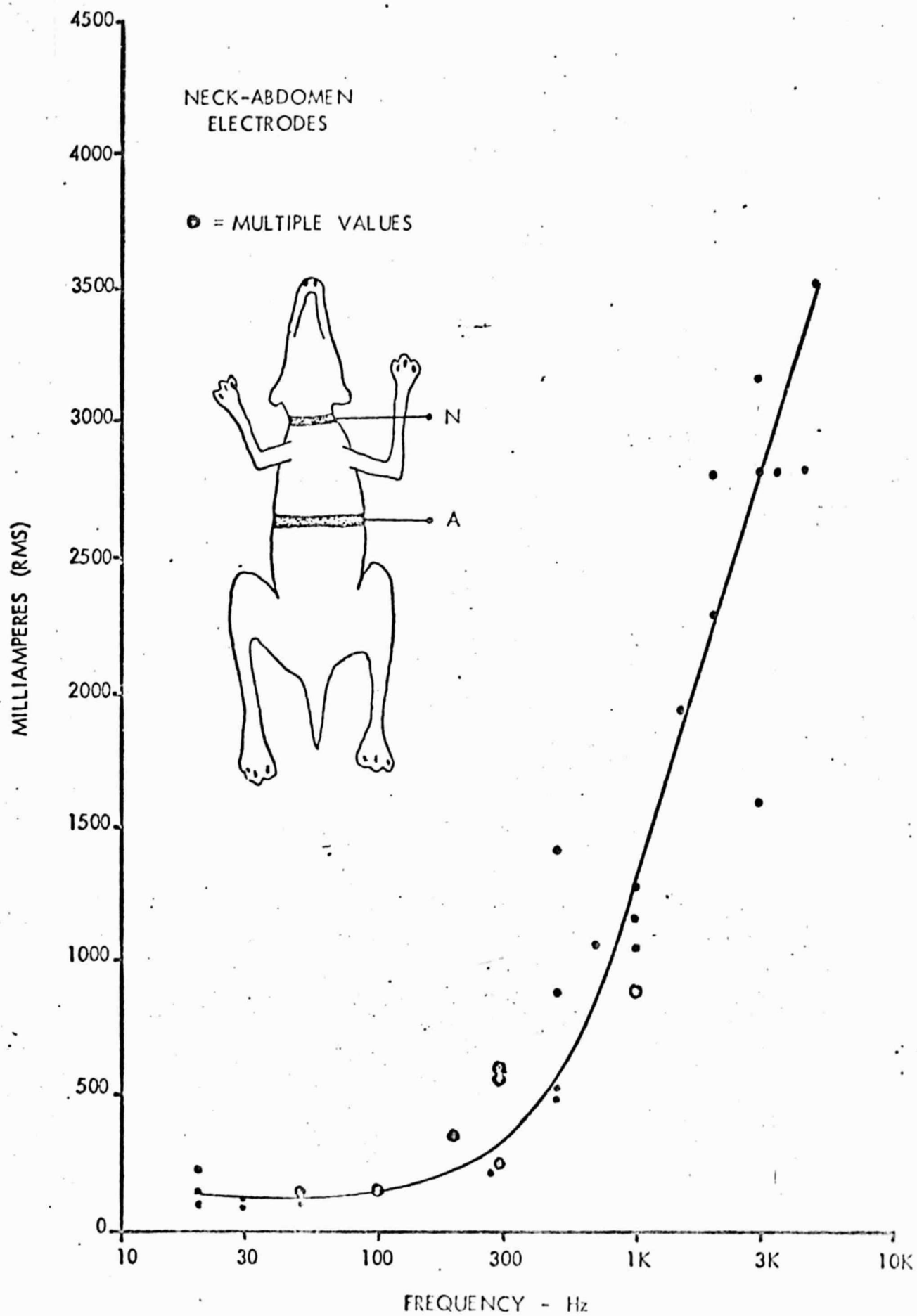
The intensity of sinusoidal current for perception was measured over a frequency range extending from 20 Hz to 10 kHz. Figure 1 shows the average current thresholds. Quite obvious is the fact that the current required for sensation increased with frequency above about 60 Hz. Also apparent is the fact that more current was required at all frequencies with the larger area neck-abdomen electrodes. (These findings are consistent with those of Dalziel (1956) who studied the current for sensation on the hand.) The current density for sensation at 60 Hz with the transchest disk electrodes was  $0.28 \text{ mA/cm}^2$  and that for the ribbon electrode around the neck was  $0.026 \text{ mA/cm}^2$ . At 10 kHz, the corresponding current densities required for sensation were 13.0 and 44.6 times those required at 60 Hz, clearly calling attention to the desirability of using frequencies at or above 10 kHz to minimize the risk of sensation and still allow passage of enough current to detect impedance changes easily.

#### VENTRICULAR FIBRILLATION THRESHOLD

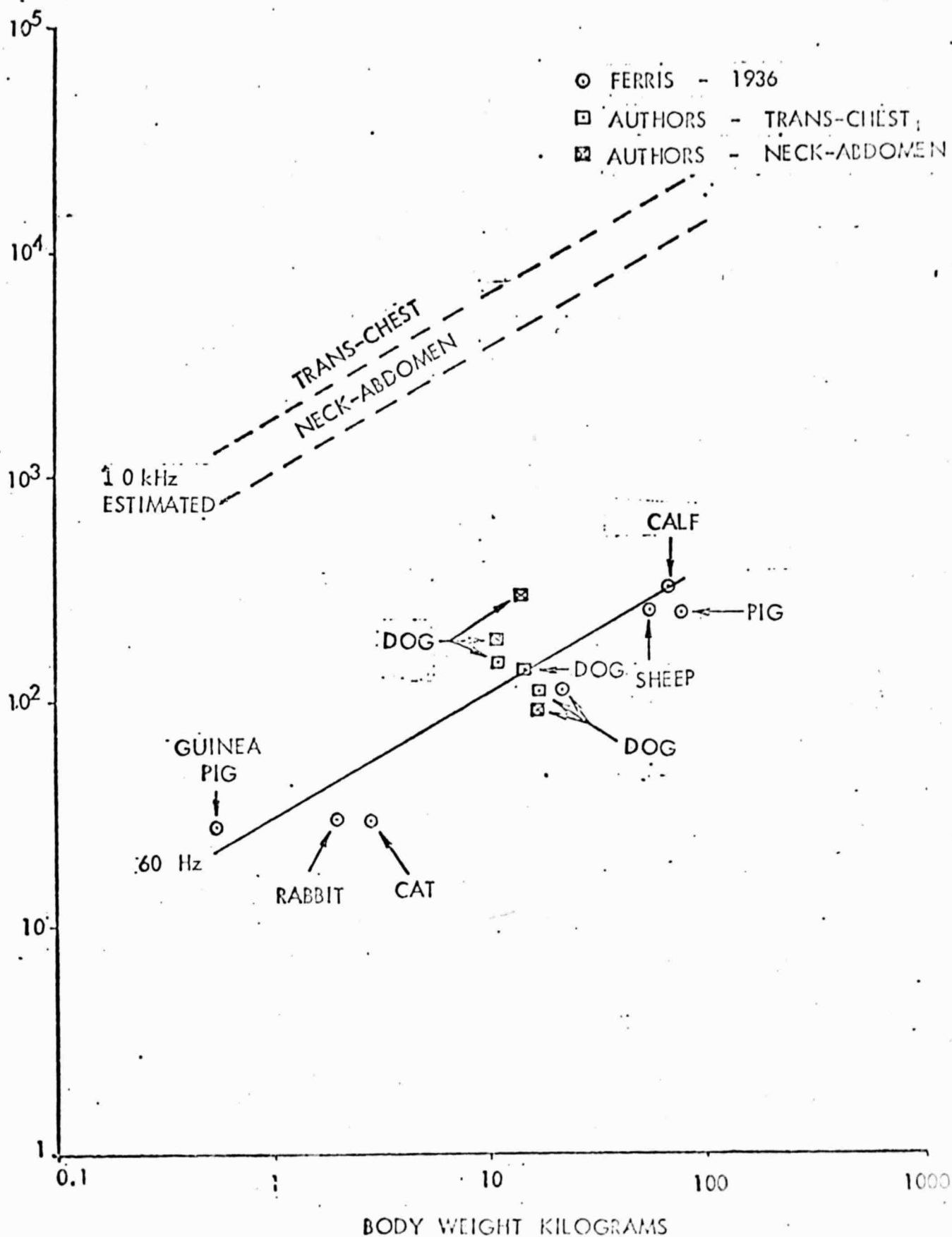
Apart from avoidance of stimulation of sensory receptors is the need to keep the transthoracic current sufficiently low to prevent stimulation of the heart and to avoid any risk of producing ventricular fibrillation. The thoracic current required for the production of ventricular fibrillation in man is not known accurately, nor is it permissible to measure it; however, data can be acquired on small and large animals and extrapolated to man. To obtain such information, the current for the production of fibrillation was measured in 4 dogs (12-18 kg) anesthetized with pentobarbital (30 mg/kg).

Sinusoidal current was applied to two sets of electrodes. The first set consisted of transchest oval (8 x 10 cm) lead plates located at the level of the fifth pair of ribs along mid-axillary lines; the second set consisted of bare braided wire (1/2" wide) placed around the neck and abdomen. These two locations were chosen to simulate respectively the current pathways for impedance respiration and stroke volume using the impedance method. Blood pressure and the electrocardiogram were recorded to identify the onset of fibrillation. The test procedure consisted of choosing a frequency and increasing the current slowly while watching the animal and blood pressure carefully. A consistent sequence of events occurred as the current magnitude was increased (Geddes and Baker, 1969). First strong contraction of skeletal muscles was observed, followed by respiratory arrest, slowing of the heart, and finally ventricular fibrillation. The heart was immediately defibrillated by passage of a high intensity 60 Hz current through the transthoracic electrodes.

Figure 2 shows the amount of transthoracic current required to produce ventricular fibrillation and Fig. 3 shows the amount of current required when applied to the neck-abdomen electrodes. Quite apparent is the fact that the current required increased with increasing frequency, particularly above 300 Hz. For the transthoracic electrodes the average current required for fibrillation at 60 Hz was 150 mA and that required with the neck-abdomen electrodes was 125 mA, i. e., slightly less current was required with neck-abdomen electrodes than with transchest electrodes. At 60 Hz the ratio is about 1.2 which, although smaller, is consistent with values found by Kouwenhoven et al. (1932) who reported values on the order of 3. At 3 kHz fibrillation was achieved with a transthoracic current of 4200 mA and a neck-abdomen current of 2800 mA; the



THORACIC CURRENT (mA) FOR VENTRICULAR FIBRILLATION



ratio of these currents is 1.5. Extrapolation of the curves in Figs. 2 and 3 indicates that at 10 kHz a transthoracic current of 8800 mA and a neck-abdomen current of 4380 mA would be required to produce ventricular fibrillation. The ratio of transthoracic to neck-abdomen current at this frequency is about 2. More important, however, are the ratios of currents at 60 kHz to those at 10 kHz required to produce ventricular fibrillation. For the transthoracic electrodes the ratio is 58.6 and for the neck-abdomen electrodes it is 35.0.

#### THE IMPORTANCE OF FREQUENCY

It is of interest to compare the increase in current required for sensation in the human with the increase in current required to produce ventricular fibrillation in the dog as frequency is increased; Table 1 makes this comparison. In both situations considerably more current is required as frequency is increased indicating the relative safety of higher frequencies.

#### FIBRILLATION THRESHOLD IN LARGE ANIMALS AND MAN

To estimate the thoracic current required to produce ventricular fibrillation in man, it is necessary to obtain the fibrillation thresholds for animals with body weights which approximate those of man. A study by Ferris et al. (1936) provides additional data for relating the current necessary to produce fibrillation with different body weights. Fig. 4 shows the average 60 Hz thoracic current required for fibrillation as measured by the authors (dogs) and the 60 Hz current values reported by Ferris et al (guinea pig, rabbit, cat, sheep, calf, pig). The least-squares line in this illustration shows that with increasing body weight, more thoracic current is needed to produce



fibrillation. For a 150 lb subject it would appear that a total current of about 320 mA (rms) at 60 Hz applied to the surface of the thorax in either a longitudinal or transverse direction will produce ventricular fibrillation. This value is consistent with Dalziel's (1956) estimate.

The frequencies employed to measure physiological events by the impedance method are much higher than 60 Hz. To estimate the current level for fibrillation with higher frequency current, the relationship between current magnitude and frequency derived from the dog (Figs. 2, 3 and Table 1) was used. The ratio of current at 10 kHz to that at 60 Hz for transthoracic electrodes is 58.6 and that for neck-abdomen electrodes is 35.0. These ratios can be used to estimate the approximate value for 10 kHz current required to produce ventricular fibrillation. Using these values to plot lines in Fig. 4, it can be seen that a very considerable 10 kHz current is required for fibrillation even in subjects with a low body weight. For a 150 lb subject it is estimated that about 11 amperes of 10 kHz transthoracic or 18 amperes of neck-abdomen current is required to produce ventricular fibrillation.

## CONCLUSION

The data presented in this paper show that the hazards of stimulation of sensory receptors and producing ventricular fibrillation are minimized by the use of high frequency current (i. e., 10 kHz or above). Table 1 summarizes the data obtained and shows that the current required increases by about 1 order of magnitude between 60 Hz and 10 kHz. From the slopes of the curves in Figs. 1-3, it is seen that beyond 10 kHz the threshold currents for sensation and ventricular fibrillation continue to increase with increasing frequency, favoring the choice of frequencies in this region.

TABLE I

RATIOS OF CURRENT AT 10 kHz TO CURRENT AT 60 Hz

Electrode Location	Sensation	Fibrillation
Transthoracic	13.0	58.6
Neck-Abdomen	44.6	35.0

The choice is made even more attractive when the nature of the strength-duration curves for irritable tissue are considered because with pulse durations of less than 20  $\mu$ sec it is almost impossible to excite any irritable tissue regardless of the amplitude of the stimulating current. On this basis it is logical to select frequencies above 50 kHz for measuring physiological events by impedance.

There are as yet no data on the sensation threshold for electrodes placed on the scalp (as in electroencephalography and rheoencephalography), around the eye (as in electro-oculography), on the chest and extremities (as in electrocardiography) and on the members (as in impedance plethysmography). Current thresholds for sensation with electrodes in these locations will be the subject of a future report.

## FIGURE LEGEND

- FIGURE 1 Threshold of sensation for sinusoidal alternating current applied to neck-abdomen (NA) and trans-thoracic (TT) electrodes.
- FIGURE 2 Threshold for ventricular fibrillation in the dog for sinusoidal alternating current applied to trans-thoracic electrodes.
- FIGURE 3 Threshold for ventricular fibrillation in the dog for sinusoidal alternating current applied to neck-abdomen electrodes.
- FIGURE 4 Threshold for ventricular fibrillation for sinusoidal alternating current in animals with various body weights.

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